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(54) Title: STERILIZATION PROCESS AND COM	MPOSI	ion
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#### TITLE OF THE INVENTION

#### STERILIZATION PROCESS AND COMPOSITION

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#### TECHNICAL FIELD OF THE INVENTION

The present invention relates to the field of sterilization of packaging materials in connection with the use of said materials for the packaging of substances which must not be contaminated with microorganisms, for instance food stuffs and beverages. More specifically the invention is within the field of sterilization of such materials by means of hydrogen peroxide as the sterilization agent.

#### BACKGROUND OF THE INVENTION

For certain packaging material grades, especially such materials which are intended to be used for food stuffs, beverages, etc., a sterilization of the surface thereof is required in order to minimize the contribution of microorganisms from the packaging material to the product to be contained therein. One of said sterilization methods involves the use of hydrogen peroxide as the sterilization agent. There are different methods of applying said hydrogen peroxide to the packaging material, such as by passing the packaging material through the hydrogen peroxide, immersing said material in said hydrogen peroxide, applying a film of hydrogen peroxide to the surface of the packaging material, etc., but generally the hydrogen peroxide is utilized in the form of a solution there-

Although the packaging material has generally been made hydrofobic during the manufacture thereof, in order to make it resistant to the penetration of aqueous liquids, including a hydrogen peroxide solution, the hydrosen peroxide is usually utilized in such a concentration and at such a temperature that a penetration thereof into the packaging material is not easily avoided. The hot

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aqueous hydrogen peroxide solution especially penetrates
the edges of the packaging material, but also in a case
where for some reason the packaging machine has to be
stopped, there will be a great risk of having a penetration of the hot hydrogen peroxide into the packaging material to loosen up the same. When restarting the machine
part of the packaging material has to be discarded or else
there will be a risk of having a bursting of any package
inside the machine which means a cleaning operation for
several hours.

Thus, in summary, there is no available system today which will impart to the packaging material such a degree of hydrofobicity that a penetration of a concentrated and hot hydrogen peroxide solution is avoided.

### OBJECT OF THE INVENTION

The main object of the present invention is to modify
the previously known sterilization process where a solution of hydrogen peroxide is utilized to manufacture an
aseptic packaging material so as to greatly reduce the
20 penetration, especially the edge penetration, of the hydrogen peroxide solution into the packaging material.
Other objects of the invention will be appearent to a person skilled in the art when reading the description of the
present invention.

## GENERAL DESCRIPTION OF THE INVENTION

According to the present invention it has been shown that the above-mentioned object can be achieved by the addition of a salt to the hydrogen peroxide solution, which salt counteracts the penetration of the hydrogen peroxide into the packaging material. Thus, in accordance with the present invention it has been found that said penetration may be decreased or reduced with at least 50%, which means a very significant improvement within the art of manufacturing aseptic packages, as said manufacturing 35 takes place at very high rates and quantities.

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More specifically the invention relates to a process for the sterilization of the surface of a packaging material by contacting said material with a hydrogen peroxide solution, characterized by modifying the hydrogen peroxide 5 solution by the addition thereto of a penetration-reducing amount of a penetration-reducing salt.

The invention also relates to a composition which is useful for the sterilization of the surfaces of a packaging material of the type referred to, which comprises a 10 hydrogen peroxide solution, characterized in that it comprises a penetration-reducing amount of a penetration--reducing salt.

### DETAILED DESCRIPTION OF THE INVENTION

Generally the process according to the invention is 15 applicable to the sterilization of any packaging material for which hydrogen peroxide solutions have been previously utilized. Especially interesting packaging materials in connection with the invention are, however, paper board and more specifically a hydrophobated board. With refe-20 rence to hydrophobated board this generally means that the board has been coated with a hydrophobic film such as plastic or wax according to any known technique. Such packaging materials are for instance utilized in the packaging of different beverages, e.g. long life milk.

Now that the inventive idea has been disclosed it should be possible to a person skilled in the art to determine whether any salt will be useful for the practice of the invention or not. Generally, however, the requirement as to the penetration-reducing salt is that it is 30 reasonably soluble in the hydrogen peroxide solution and that it does not catalyze the decomposition of the hydrogen peroxide to any substantial extent, i.e. not to such an extent that the sterilization effect is adversely influenced upon. Expressed in another way a suitable pene-35 tration-reducing salt for use in accordance with the invention includes any salt which reduces the penetration of a hydrogen peroxide sterilization solution into a hydro-

phobated board and which is compatible with the hydrogen peroxide solution is useful in accordance with the invention. Compatible in this sence may e.g. mean that the hydrogen peroxide concentration is not reduced to any sub-5 stantial extent, for instance not more than 10%, or not more than 5%, during 1 week or even 2 weeks.

According to the invention it has been found that for instance alkali metal salts are preferable as to the non--penetration of the hydrogen peroxide. An especially pre-10 ferable embodiment of the process of the invention means that a sodium salt is utilized.

Other potential salts for use in accordance with the invention may be selected from the group of alkaline earth metals, especially calcium and magnesium. Furthermore, 15 aluminium salts should be useful in accordance with the invention.

According to another preferable embodiment of the invention the hydrogen peroxide solution is modified with a salt selected from the group consisting of sulphates and 20 halogenides, preferably chlorides.

From the above-mentioned it can also be gathered that specifically interesting salts for the modification of the hydrogen peroxide solution are sodium sulphate and sodium chloride.

The salt referred to is generally used in a penetration-reducing amount, which should be easily determinable by a person skilled in the art, especially by means of the Wick index method which will be described more in detail below. However, a penetration-reducing amount of said salt 30 is a concentration which reduces the Wick index of the paper board preferably by at least 20%, more preferably by at least 30% and most preferably by at least 40%. Generally, the solubility of the salt in hydrogen peroxide dictates the upper limit of the concentration range. 35 However, in order to minimize the depositions of salts in the packaging machine a concentration as low as possible is aimed at. A preferable salt concentration may also be

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defined as 0.5-1 mole/litre. Toxicity considerations should of course also be taken in the usual way when food stuffs and beverages are involved.

With reference to the contact between the packaging 5 material and the hydrogen peroxide solution said contact is generally performed in accordance with the prior art, which preferably means that a hot aqueous hydrogen peroxide solution is used. The term hot is used in a broad meaning in accordance with the known technique, but 10 according to a preferable embodiment of the process of the invention the temperature of the hydrogen peroxide solution is within the range of 50-80°C, especially good results being achieved at a temperature of the order of 70°C.

The concentration of the hydrogen peroxide solution, i.e. as to the contents thereof of H2O2, is generally similar to that used according to the prior art. However, a preferable embodiment of the present invention involves the use of a solution that is 10-40% as to its hydrogen 20 peroxide content, the percentage being calculated in accordance with current practice within this field. Especially preferable results are generally achieved with a hydrogen peroxide solution having a concentration of the order of 35%.

Also with reference to the pH-value of the hydrogen peroxide solution the general principles of the current art are applicable. Thus, also with the addition of the salt in accordance with the invention, which salt may well influence upon the pH of the solution, the previously 30 known pH ranges are useful. Especially preferable results as to non-penetration in accordance with the invention are, however, obtained at a pH-value of the modified hydrogen peroxide solution within the range of 1-4, the range of 1.5-2.5 being especially preferable.

The contact between the packaging material and the modified hydrogen peroxide solution can take place in accordance with any one of the known techniques. Thus, in

this respect, reference is made to the prior art as concerns details of the different techniques utilized. According to a preferable embodiment of the process claimed the packaging material is, however, contacted with the bydrogen peroxide solution by passing the material therethrough in a continuous way.

Preferable embodiments of the composition according to the invention are the same as have been described in connection with the process claimed and will not be re-10 peated here.

The process as well as the composition according to the invention will now be more specifically illustrated by means of the following non-limiting examples.

#### EXAMPLES

142 g of sodium sulphate were added to one litre of hydrogen peroxide. The concentration of the hydrogen peroxide was adjusted to 35%.

A plastic coated board was prepared and immersed into hot (70°C) hydrogen peroxide solution for 10 minutes and 20 the amount of liquid which had penetrated into the board was determined in accordance with the edge wicking method that will be described below and expressed as the Wick index. The Wick index was found to be 0.5 kg/m² which should be compared to a corresponding Wick index value of 25 0.9 kg/m² for a control (i.e. without any addition of salt).

The above experiment was repeated with sodium chloride in different concentrations. The addition of the salt means that the concentration or percentage of the hydrogen peroxide is reduced, and in addition thereto it was found that the pH decreased. Therefore, if the specifications for the Wick test are to be followed one has to start from a hydrogen peroxide having a higher concentration than the one desired and optionally adjust the concentration and pH after the addition of the salt. The solutions tested are presented in Table 1. Furthermore, NaHCO<sub>3</sub> was also tested but a slow evolution of gas was

noted which indicates that it catalyzes the decomposition of the hydrogen peroxide. Thus, the test with  ${\tt NaHCO}_3$  was discontinued.

5	TABLE 1					
	Test	Weight %	рН			
	35% H <sub>2</sub> O <sub>2</sub>	36.0	2.30			
	+1.0 M NaCl	34.1	1.64			
10	+2.0 M NaCl	32.4	1.60			
	+3.0 M NaCl	30.7	1.49			

With the above-mentioned solutions the edge penetration measurements were made, and in Table 2 the results 15 thereof are presented.

TABLE 2

20	Test	Wick (I) (kg/m <sup>2</sup> )	Wick (II) (kg/m <sup>2</sup> )
	35% H <sub>2</sub> O <sub>2</sub>	1.15	0.96
	+1.0 M NaCl	0.79	0.66
25	+2.0 M NaCl	0.65	0.52
	+3.0 M NaCl	0.55	0.45

In this case Wick (I) means that the pH-value was not adjusted after the salt addition while Wick (II) refers to 30 such a pH adjustment. As is clear from this table the adjustment of the pH was of marginal influence only.

In order to investigate the effects of the dilutions obtained by the salt additions some experiments were made where the 36% hydrogen peroxide was diluted to 34% and 35 30%, respectively. The results thereof are presented in Table 3.

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TABLE	3

5	Cona.	Wick (kg/m <sup>2</sup>
	36	0.91
	34	0.88
	30	0.81

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As can be seen the effect of a lower hydrogen peroxide concentration is a lower Wick value. The value obtained for 30% hydrogen peroxide should be compared to the value obtained with 3M NaCl (0.45-0.55 kg/m $^2$ ).

Then the effects of NaCl with a proper hydrogen peroxide concentration (35%) and with adjusted pH values were investigated. The results thereof are presented in Table 4.

### 20 TABLE 4

Test	Wick (kg/m <sup>2</sup> )
Blank 35%	0.92
+2M NaCl	0.61
+3M NaCl	0.57
	Test Blank 35% +2M NaCl

As is clear from the above Table the results for 30 added salts are significantly superior also when the hydrogen peroxide concentration is the proper one according to the test method.

The first result presented above with reference to sodium sulphate was supplemented with additional results as to sodium sulphate in accordance with Table 5 below.

TABLE 5

5	Test	Conc. (%)	Wick (kg/m <sup>2</sup> )	рН
	Blank	35	0.91	2.4
	1M Na2SO4	31.8	0.57	2.8 direct
	1M Na <sub>2</sub> SO <sub>4</sub>	31.8	0.49	2.4 adjusted pH
10	1M Na <sub>2</sub> SO <sub>4</sub>	35.0	0.49	2.4

As can be seen from the above-mentioned Table, contrary to what was obtained by the addition of sodium chloride, the pH value increased by the addition of the 15 sulphate. Furthermore, it can be seen that the effect on the Wick value is higher with the sodium sulphate. Thus, with 1M Na2SO4 the result is similar to that obtained with 3M NaCl.

Different other salts were also tested in a way simi-20 lar to that described above. The results thereof as to decomposition of hydrogen peroxide are presented in Table 6, the concentration being chosen so as to obtain an ionic strength of 3.0.

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	TABLE 6				
	Salt	Conc.	Conc.	Conc. 1 week	Conc. 2 weeks
		(M)	directly		
			(% by	(% by weight	(% by weight
5			weight of	of H <sub>2</sub> O <sub>2</sub> )	of H <sub>2</sub> O <sub>2</sub> )
			H <sub>2</sub> O <sub>2</sub> )		
	Na4P2O7	0.3	47.0		43.6
	Na Acetate	3.0	33.8		31.1
10	CaCl <sub>2</sub>	1.0	44.4		42.2
	Alum*	0.2	44.4		0.5
	Na <sub>2</sub> SO <sub>4</sub>	0.5	34.9	34.9	
	Na <sub>2</sub> SO <sub>4</sub>	1.0	44.7	44.5	
	Na2SO4	2.0	39.9	39.8	
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Also  $Na_3PO_4$  was tested but said test was discontinued due to gas evolution indicating the decompostion of the 20 hydrogen peroxide.

As is clear from Table 6 the decomposition of the hydrogen peroxide varies to a great extent with the different salts used. The bad result obtained with alum is probably due to the presence of iron therein.

The effects of the salts above, except for alum were tested at 70°C with the hydrogen peroxide concentration adjusted to 35%. As is seen in Table 6 above the hydrogen peroxide concentration falls below 35% if 3.0M Na acetate is used. As 50% hydrogen peroxide was initially used, it 30 was not possible to use more than 2.76 moles per liter of sodium acetate.

The results are presented in Table 7.

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\*Al2(SO4)3

TABLE	7
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	Salt	Conc.	Wick
		(M)	(g/m <sup>2</sup> )
5			
	Na <sub>4</sub> P <sub>2</sub> O <sub>7</sub>	0.3	1.6
	Na Acetate	2.76	1.8
	CaCl <sub>2</sub>	1.0	0.86
	Na <sub>2</sub> SO <sub>4</sub>	0.5	0.85
10	Na <sub>2</sub> SO <sub>4</sub>	1.0	0.55
	Na <sub>2</sub> SO <sub>4</sub>	2.0	0.54
	Blank		1.5

One test was also made at 60°C, viz. with 1 M of

15 Na<sub>2</sub>SO<sub>4</sub>. The result was comparable to that obtained at 70°C

(Table 6 above).

Finally, with reference to the Wick values referred to above, the following test method was used.

EDGE WICKING OF SIZED PAPER AND PAPER BOARD 20 (70°C, 10 min 35% hydrogen peroxide)

#### DEFINITION

The edge wicking test is a method to determine how well a paper is sized against the specified test solution.

The edge wicking index (EWI) in this test is defined 25 as the amount of liquid absorbed by the edges of test pieces placed for 10 minutes in hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>).

The result is given in kg/m<sup>2</sup> and the testing condi-

tions (time and temperature) must be reported.

#### EQUIPMENT

- water bath with thermostat
- analytical balance (with readability of 0.1 mg)
- guillotine
- stop watch
- tape, water resistant e.g. Scotch El-tape No. 5 from 3M Co

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- dish, e.g. crystallizing dish of Duran glass
- rods of glass or stainless steel
- measuring glass
- beaker
- 5 blotting paper
  - thermometer (with readability of 1°C)

## TEST SOLUTION

Hydrogen peroxide (Food grade) 35% by weight. Density  $1130~{\rm kg/m}^3$ . pH 1.5 to 2.5. (same quality as used in AB8 10 and AB9).

#### TEST PROCEDURE

## Preparation of test pieces

The raw paper should be conditioned according to TP 85013 (modified SCAN P2:75).

15 TP 85013 specifies:

Preconditioning at 60°C for 30 minutes and the conditioning at 23°C  $\pm$  1°C and 50% RH  $\pm$  2% RH for at least 3 hours.

For <u>raw paper</u> cover the printing and the back sides of the test material carefully with water resistant tape. Make sure there are no air bubbles between the paper and the tape.

For <u>laminated material</u> tape is not necessary. Cut out 10 test pieces. Two (2) series with five (5) test samples in each. The test pieces should be

25 mm (MD) x 75 mm (CD).

Please note that the cutting edges of the guillotine must be sharp in order to get well cut edges.

The edges must be pressed against each other and the test plece removed before the cutting edges are separated, otherwise the fibre structure of

## Thickness measurement

the edges can be disturbed.

Measure the thickness of the sample. For <u>laminated</u>

35 <u>material</u>, the thickness for polyethylen and aluminum foil should be subtracted.

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Only the paper thickness is needed. A mean value of the thickness for five test pieces should be used in the calculations.

#### Edge wicking test

Weigh each series of five (5) test pieces together up to the nearest mg on an analytical balance. At least two (2) series are preferable. Pour hydrogen peroxide in a flat bottomed glass dish. Place the glass dish in a water bath and 10 wait until the hydrogen peroxide has reached 70°C ± 1°C.

> Place the test pieces in the glass dish so they do not touch each other and put glass rods on top. Make sure that the test pieces are covered by 10 mm ± 1 mm of hydrogen peroxide.

> Remove the test pieces after 10 minutes ± 15 seconds and place them between two blotting papers and wipe off excessive liquid. Avoid hard pressing on the surface and avoid touching the edges. During these operations wear gloves and safety

glasses (see Appendix 1). The water bath with the peroxide should preferably be placed in a closed hood or under a well ventilated hood.

25 Weigh at once each series of five (5) test pieces together up to the nearest mg. Note:

> Hydrogen peroxide may evaporate during tests. Hence, it is necessary to add more hydrogen peroxide so the test pieces always are covered with 10 mm ± 1 mm of liquid.

Start every day's measurements with fresh solution of hydrogen peroxide.

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### CALCULATION

W<sub>1</sub> = weight before (mg) contact with hydrogen peroxide

W<sub>2</sub> = weight after (mg) contact with hydrogen peroxide

t = thickness ( $\mu m$ ), a mean value for five (5) test pieces

 $\lambda$  = sample edge length (m) 1 m

Edge wicking index = 
$$\frac{W_2 - W_1}{\lambda \times t}$$

For each series of five (5) test pieces:

$$\lambda$$
 = 1, i.e. 5 x (75 mm + 75 mm + 25 mm + 25 mm) = 1000 mm = 1 m

Edge wicking index (EWI) = 
$$\frac{W_2 - W_1 \text{ (mg)}}{\text{t (um) x 1 m}}$$

which gives a value in the unit  $kg/m^2$ 

#### Remark 1

25 If the thickness of the base board is unknown the edge wicking value (EWV) should be reported as mq/m.

Hence, for each series of five (5) test pieces  $\lambda = 1$ , i.e. 5 x (75 mm + 75 mm + 25 mm + 25 mm) = 1000 mm = 1 m

Edge wicking value (EWV) = 
$$\begin{bmatrix} w_2 - w_1 \pmod{mg} \\ & & \end{bmatrix}$$
 [mg/m]

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The edge wicking index will be reported in  $kg/m^2$ . Temperature and time must be specified.

If two or more series are carried out, a mean value should be reported.

### 16 CLAIMS

- A process for the sterilization of the surfaces
  of a packaging material, especially board and more specifically hydrophobated, e.g. plastic coated, board, by contacting said material with a hydrogen peroxide solution,
  characterized by modifying the hydrogen peroxide solution
  by the addition thereto of a penetration-reducing amount
  of a penetration-reducing salt.
- A process according to claim 1, characterized by
   modifying the hydrogen peroxide solution with an alkali metal salt, perferably a sodium salt.

3. A process according to claim 1, characterized by modifying the hydrogen peroxide solution with an alkaline earth metal salt, preferably a calcium or magnesium salt, 15 or an aluminium salt.

- 4. A process according to any one of claims 1, 2 and 3, characterized by modifying the hydrogen peroxide solution with a salt selected from the group consisting of sulphates and halogenides, preferably chlorides.
- 20 5. A process according to any one of the preceding claims, characterized by modifying the hydrogen peroxide solution with Na,SO, or NaCl.
- 6. A process according to any one of the preceding claims, characterized by modifying the hydrogen peroxide 25 solution with said salt in an amount which reduces the Wick index by at least 20%, more preferably at least 30% and most preferably at least 40%, relative to the Wick index obtained without the addition of said salt.
- 7. A process according to any one of the preceding 30 claims, characterized by contacting said material with a modified hot aqueous hydrogen peroxide solution, preferably with a temperature within the range of 50-80°C, especially around 70°C.
- 8. A process according to any one of the preceding 35 claims, characterized by contacting said material with a modified 10-40%, preferably around 35%, hydrogen peroxide solution.

- 9. A process according to any one of the preceding Claims, characterized by contacting said material with a modified hydrogen peroxide solution, the pH of which is within the range of 1-4, preferably 1.5-2.5.
- 10. A process according to any one of the preceding claims, characterized by contacting said material with the hydrogen peroxide solution by passing the material therethrough, preferably in a continuous way.
- 11. A composition which is useful for the sterilization of the surfaces of a packaging material, especially board and more specifically hydrophobated, e.g. plastic coated board, comprising a hydrogen peroxide solution, characterized in that it comprises a penetration-reducing amount of a penetration-reducing salt.
- 15 12. A composition according to claim 11, characterized in that the penetration-reducing salt is an alkali metal salt, preferably a sodium salt.
- A composition according to claim 11, characterized in that the penetration-reducing salt is an
   alkaline earth metal salt, preferably a calcium or magnesium salt, or an aluminium salt.
- 14. A composition according to any one of claims 11-13, characterized in that the penetration-reducing salt is selected from the group consisting of sulphates and halo-25 genides, preferably chlorides.
  - . 15. A composition according to any one of claims 11-14, characterized in that the penetration-reducing salt is  $Na_{\alpha}SO_{\alpha}$  or NaCl.
- 16. A composition according to any one of claims 11-30 15, characterized in that the penetration-reducing salt is present in an amount which reduces the Wick index by at least 20%, more preferably at least 30% and most preferably at least 40%.
- 17. A composition according to any one of claims 11-35 16, characterized in that the hydrogen peroxide content is 10-40%.

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	<ol><li>18. A composition according to any one of cla</li></ol>	ims 11-
17,	, characterized in that the hydrogen peroxide so	olution
has	s a pH within the range of 1-4, preferably 1.5-2	2.5.

## INTERNATIONAL SEARCH REPORT

International application No.

### PCT/SE 93/00604 A. CLASSIFICATION OF SUBJECT MATTER IPC5: A61L 2/18, B65B 55/10 According to international Patent Classification (IPC) or to both national classification and IPC B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) IPC5: A61L, B65B Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched SE.DK.FI.NO classes as above Electronic data base consulted during the international search (name of data base and, where practicable, search terms used) C. DOCUMENTS CONSIDERED TO BE RELEVANT Relevant to claim No. Citation of document, with indication, where appropriate, of the relevant passages X 1,4,6-8, GB, A, 1099293 (TEPAR A.G.), 17 January 1968 10-11,14, (17.01.68), page 2, line 108 - line 115, claims i-3 16-17 Chemical Abstracts, Volume 98, No 7, 14 February 1983 (14.02.83), (Columbus, Ohio, USA), 1-18 Α page 538, THE ABSTRACT No 52223t, JP, A2, 57153873, (KOKAI TOKKYO KOHO) 22 Sept 1982 (22.09.82) P.A WO, A1, 9219287 (SOLVAY INTEROX LIMITED), 1-18 12 November 1992 (12.11.92), page 4, line 2 - line 9; page 4, line 34 - line 38 X See patent family annex. Further documents are listed in the continuation of Box C. "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relev "E" erlier document but published on or after the international filing date "X" document of particular relevance: the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "Y" document of particular relevance: the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combinati-being obvious to a person stilled in the art "O" document referring to an oral disclosure, use, exhibition or other "P" document published prior to the international filing date but later than "&" document member of the same patent family the priority date claimed Date of mailing of the international search report Date of the actual completion of the international search 0 5 -10- 1993 28 Sept 1993 Authorized officer Name and mailing address of the ISA/

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# INTERNATIONAL SEARCH REPORT

International application No.

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